

Lysonox® ULTRASHIELD

with boosted disinfection effect

Ready to use disinfectant and cleaner, with a broad spectrum of action, for the simultaneous disinfection and cleaning of surfaces, furnishings and non-immersible medical devices.

FEATURES

Lysonox® ULTRASHIELD is a ready to use liquid product for the simultaneous cleaning and disinfection of surfaces, furnishings and non-immersible medical devices (e.g. handpieces, cables, orthopedic power tools, etc.). The special formulation combines the stabilized Hydrogen Peroxide with alcohol, forming a biocidal pool capable of having a complete spectrum of activity, till against the spores. The absence of chlorinated agents or aldehyde derivatives also make Lysonox® ULTRASHIELD a safe product and compatible with various types of materials. The dispensing takes place directly by nebulizing the product through the dedicated trigger, which avoids unnecessary dispersions in the air and allows greater safety for the operator. Finally, the spectrum of action makes Lysonox® ULTRASHIELD very versatile to cover the various needs of reducing the microbial load, even in very critical situations (such as in intensive care unit, etc.)

SPECIAL PROPERTIES AND CLINICAL BENEFIT

- Ready to use broad spectrum product
- Without aldehydes and derivatives
- Without chlorinated agents
- No need to rinse
- Does not leave any kind of residue
- Dedicated dispenser for maximum safety and economy of use
- High compatibility with materials
- Suitable for all non-immersible surfaces of furnishings and medical devices
- Designed to break down the microbial load even in critical situations
- Product stability from the first dispensing: 12 months
- Fast: contact time from 5 min to 30 min

FIELDS OF USE

Lysonox® ULTRASHIELD is indicated for the following fields of use:

- Intermediate to high level cleaning and disinfection of surfaces, furnishings and non-immersible medical devices compatible with alcohol and oxidizing substances.





CONTACT TIME AND USE

Low-level disinfection (bactericidal and yeastocidal activity)	Ready-to-use	5 min
Intermediate level disinfection (bactericidal, fungicidal, mycobactericidal and virucidal activity)	Ready-to-use	15 – 30 min
High level disinfection (with mechanical action)	Ready-to-use	15 min

Lysonox® ULTRASHIELD is a ready-to-use product and therefore must not be diluted. Dispense the product directly onto the surface to be treated or indirectly using a non-woven cloth or sponge to distribute the product. Do not rinse (unless the treated medical device requires it).

Since Lysonox® ULTRASHIELD, if used for common surfaces, must not be rinsed, the contact times indicated in the relative table will potentially always be respected. If necessary, dry the excess product.

Before using Lysonox® ULTRASHIELD, it is advisable to check that the material to be treated is compatible with alcohol and oxidizing substances.

Do not dispense on flame or incandescent surfaces.

MECHANISM OF ACTION

The biocidal system of Lysonox® ULTRASHIELD allows to have a broad spectrum of action up to the spores (*B.Subtilis*). In particular:

Hydrogen peroxide:

Hydrogen peroxide is a powerful biocide as it generates free radicals which are produced in contact with the metal ions present in the substrate or produced by the metabolism of the bacteria themselves. Hydrogen peroxide acts with an oxidative reaction on the sulfhydryl bonds -SH, -S-S- and the double bonds present in proteins, enzymes and other membrane metabolites, with consequent protein denaturation and death of the microorganism.

Alcohol

The alcoholic complex used acts by denaturation and coagulation of proteins at the level of the wall, the cytoplasmic membrane and the cytoplasm. The different phenomena observed constitute upheavals of cytoplasmic integrity, with cell lysis and interference on cellular metabolism. This process is optimized in the presence of water, which facilitates the penetration inside the bacterial cell.

The synergy between the active ingredients and the excipients present in the product allow Lysonox® ULTRASHIELD to be used easily in various situations, where high-level disinfection may also be required.



ANTIMICROBIAL ACTIVITY

The biocidal activity tests of Lysonox® ULTRASHIELD were performed according to the current standards published by the European Committee for Standardization (CEN TC 216) by Test Centers Certified as operating according to GLP (Good Laboratory Practices) and ISO 17025 certified.

Lysonox® ULTRASHIELD has a biocidal activity as follow:

Biocidal activity	EN Tests	Contact Time
Bactericide (S.Aureus, P.Aeruginosa, E.Hirae, Klesbiella Pneumoniae NDM-1 class B Carbapenemasi, Acinetobacter Baumannii, MRSA)	EN 13727* EN 17387* EN 16615* (with mechanical action)	15 min 5 min
Fungicide and Yeasticide Aspergillus Brasiliensis, Candida Albicans, Cadida Auris	EN 13624* EN 13697* EN 17387* EN 16615* (with mechanical action)	15 min 5 min
Mycobactericide (M.Terrae, M.Avium)	EN 14348	15 min
Virucide (Poliovirus, Adenovirus, Norovirus, Vaccinia virus, Coronavirus included as SARS CoV-2 virus, Rotavirus)	EN 14476* EN 16777*	30 min
High level disinfection (B.Subtilis, B. Cereus, C. Difficile)	EN 16615 EN 17486 (with mechanical action)	15 min

*Test in dirty conditions

MATERIAL COMPATIBILITY

In vitro tests carried out in the laboratory have allowed us to verify the compatibility of the product with various surfaces. The long-term effect was simulated by immersing the various materials in Lysonox® ULTRASHIELD. In fact, it has been verified that static exposure is a predictive factor of the long-term effects of hydrogen peroxide.

The samples of the various materials were immersed in the solution as they were for periods of different lengths. At established intervals (from 15 min up to 100 hours), the samples were rinsed, dried and individually examined under an optical microscope, to ascertain the possible presence of corrosion and/or degradation.

They were then re-immersed and exposure to the product continued. All the materials listed below have been tested and found to be free from corrosion, degradation and morphological and visual alteration after immersion for prolonged periods of exposure.

Lysonox® ULTRASHIELD, if used according to the indications for use, is compatible with:

- Stainless steel
- Zinc
- Copper
- Polypropylenes (PPE)
- PVC
- Polystyrene
- Teflon (PTFE)
- Polycarbonates

The use with materials such as aluminum and derivatives is not recommended. In any case, for confirmation, and in case of materials not present in this list, you can contact ADRANOX directly.



CHEMICAL-PHYSICAL DATA

Appearance: clear liquid/slight yellow
Density: 0,990 – 1,010
pH : neutral - acid

COMPOSITION

100 g of solution contains:

Stabilized hydrogen peroxide, alcohol complex, nonionic surfactant, excipients and purified water q.s. at 100

STORAGE INFORMATION

Store tightly closed and at a temperature between 5°C and 25°C, away from heat sources. Not smoking. Keep out of reach of children.

Stability: 24 months (unused product) if stored according to the indications provided. Once opened and dispensed for the first time, the product, in unopened packaging, is stable for 12 months as long as it is within the expiry date indicated on the label.

WARNINGS

Lysonox® ULTRASHIELD is a ready-to-use product for professional use only. When using, follow the warnings on the label and in the safety data sheet. Empty bottles and residual solutions must be disposed of according to current legislation.

Report any serious accident involving the user and/or patient that has occurred in connection with the use of the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CE MARKING: 0051

Lysonox® ULTRASHIELD is a class IIa medical device and meets the legal requirements for medical devices according to the Regulation 2017/745 (MDR).

PACKAGING AVAILABLE

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|---------------------------|------------------|
| • Pack. 750 ml X 12 Flac. | Cod. ADMR203.075 |
| • Pack 1000 ml X 12 Flac | Cod. ADMR203.10 |
| • Pack. 5000 ml x 4 Tanks | Cod. ADMR203.50 |

ADDITIONAL INFORMATION

ADRANOX is a certified company and operates according to the UNI EN ISO 13485:2016 standard

Contact ADRANOX directly for any information on the use of Lysonox® ULTRASHIELD according to your needs.

Manufacturer

ADRANOX srl

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The information contained is based on our knowledge as of the date indicated below. It refers to the product indicated and is not a specific guarantee of particular characteristics of the product.